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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,320	02/08/2000	SHIGETO UCHIYAMA	Q57711	1771

7590 04/28/2003

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EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/28/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/485,320	UCHIYAMA ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7 and 9-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7 and 9-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/29/03 has been entered.

Claims 1, 3-7 and 9-12 are being considered on the merits.

Claims 1, 3-7 and 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in lacking the critical limitation of "live" or "viable" for the *Streptococcus* strain. Similarly, the limitations of claim 4 requiring inclusion of "at least one component that favors the maintenance and growth of the strain" should be recited in the independent claim to clarify the invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-7 and 9-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising the specific deposited microorganisms *Streptococcus E-23-17*, and *Streptococcus A6G-225*, does not reasonably provide enablement for a composition comprising *Streptococcus intermedius* or *Streptococcus constellatus* that are capable of degrading daidzein to equol. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

From the record of the present written disclosure, the only *Streptococcus* strains demonstrated to be shown to be suitable for the claimed invention are *Streptococcus E-23-17*, and *Streptococcus A6G-225*. Therefore these are the only strains of this genus enabled by the present specification therefor. It would require undue experimentation for one skilled in the art to determine which strains of *Streptococcus intermedius* and by *Streptococcus constellatus* would have the required property of metabolizing daidzein to equol and thus be suitable for the

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claimed invention. The fact that a few selected strains of *Streptococcus* are known to have this capability would not allow one of ordinary skill in the art to determine strains within the recited species, in view of the potential diversity of strains encompassed *Streptococcus intermedius* and by *Streptococcus constellatus* and the difficulty in isolating strains from nature, especially in the absence of a specific screening assay. Ex parte Jackson, 217 U.S.P.Q. 804 (Bd. App. 1982).

Undue experimentation would also be required to determine which strains are properly *S. intermedius* and *S. constellatus* since the taxonomic status of these species is at least ambiguous. The ATCC Catalogue adequately demonstrates that strains of each of *S. intermedius* and *S. constellatus* are now classified as *S. anginosus*. The relationship between members of the species *S. intermedius* and *S. constellatus* and the strains of claim 3 in the claimed composition is not clearly set forth on this record. The proper classification to species of the deposited *Streptococcus* is not established.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary to identify strains of *Streptococcus* the ability to degrade daidzein and determination of their taxonomic identification as well as the limited amount of guidance and limited number of working examples in the specification, and the unpredictable nature of the invention and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Thus, the scope of the claims is not commensurate with the teachings of enablement of the specification.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

It is noted that the document received is the certified translation of the priority document rather than a certified copy of the priority documents, which is hereby acknowledged.

Upon cancellation of the non-allowable claims, claim 3 would be allowable if presented in independent form and if amended to clarify that the strains are viable in the composition.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

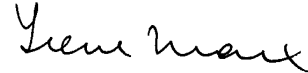
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.



Irene Marx
Primary Examiner
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